Court File Number: T-906-99

IN THE FEDERAL COURT OF CANADA
TRIAL DIVISION

Between:

INVERHURON & DISTRICT RATEPAYERS' ASSOCIATION
Applicant

and

THE MINISTER OF THE ENVIRONMENT,
THE ATOMIC ENERGY CONTROL BOARD and
MINISTER OF FISHERIES AND OCEANS
and
ONTARIO POWER GENERATION INCORPORATED
Respondents

AFFIDAVIT OF DR. DAVID HOEL

I, DAVID G. HOEL, of the City of Charleston, South Carolina, AFFIRM THAT:

1. I am a presently employed as a Distinguished University Professor at the Medical University of South Carolina and have been in this position since 1997. My teaching responsibilities include developing and teaching three courses in epidemiology to medical and graduate students. From 1992 to 1997, I was a Professor and Chairman of the Department of Biometry and Epidemiology and Associate Director for Epidemiology at the Hollings Cancer Center, also at the Medical University of South Carolina.

2. For over 20 years, I was a researcher and a research director at the National Institutes of Health, with particular emphasis on the cancer effects of chemicals and ionizing radiation. As a research director, I supervised research into epidemiology, biostatistics, and risk assessment. These fields are not mutually exclusive: biostatistics, for example, is the study of statistical methods for the design, analysis and interpretation of biomedical and epidemiological studies. In turn, risk assessment uses epidemiological, toxicological and biostatistical methods to quantitatively assess risks to human populations.

3. Over this period of time, I have carried out research into numerous cancer-related topics on both chemical and radiation effects.

4. My research into radiation topics includes two periods of employment (1979-80 and 1984-86) in Japan at the Radiation Effects Research Foundation in Hiroshima, Japan.

5. Since 1976, I have been a member of committees of the United States National Academy of Sciences. From 1986 to 1989, this included membership on the Committee on the Biological Effects of Ionizing Radiation (BEIR V). I have been and continue to be a

Council Member of the National Council on Radiation Protection and Measurements (NCRP) for two terms, 1993-1999 and 1999-2000.

6. My research has resulted in over 150 published papers, and includes specific consideration of risk estimating models for chemicals and radiation. Attached as Exhibit "A" to my affidavit is a true copy of my *curriculum vitae*.

7. For this affidavit, I have reviewed the following documents:

- affidavit of Suzana Fraser, dated October 5, 1999;

- the Atomic Energy Control Board (AECB) studies, "Childhood Leukemia around Canadian Nuclear Facilities" - Phases 1 and 2 (1989 and 1991) ("AECB child leukemia studies") (attached as Exhibits "B" and "C" to my affidavit are true copies of the Phase I and Phase II AECB studies, respectively); and

- "Childhood leukemia in the vicinity of Canadian nuclear facilities" (1993), 4 Cancer Causes and Control 51-58, found as Ex.49 to the affidavit of Normand de la Chevrotiere (hereafter, "Ex.49");

AECB child leukemia studies for areas around the Bruce and Pickering nuclear generating stations

8. The AECB child leukemia studies consist of two phases: the Phase I study considers leukemia deaths in children 0-4 years of age nearby to selected nuclear facilities; and the Phase II study considers child leukemia deaths in children 0-14 years of age nearby to the same selected nuclear facilities.

9. Both studies focus on five nuclear facilities: two nuclear stations; a research facility; and a uranium mine and a uranium refinery. The AECB study authors identify "diversity in the nature of the three general types of facilities" and note that "each would result in different potential exposures" (Phase I, p.7). On this basis, the authors concluded it was "not appropriate to pool the results across all facility types" (*ibid.*). However, the authors did pool results for the two nuclear stations. It is these findings which I believe merit specific attention.

10. The two nuclear stations show elevated levels of cancer within 25 km of the two stations studied.

11. Ms. Fraser offers two opinions about the results of these AECB studies for nuclear power stations (para.14):

(a) "Statistically significant differences between childhood leukemia rates in the 25 kilometre region of BNPD/Pickering and Ontario were not evident...";

(b) "No consistent, statistically significant, temporal pattern of risk was evident to suggest increasing rates over time."

12. I disagree with the first opinion and say that the second opinion is misleading because the data were not adequate to assess trends over time.

(a) Statistical significance

13. In statistical work such as the AECB study, a central issue is whether a finding is statistically significant. Thus, for the AECB study, a central issue is whether the 40% increase rate of childhood leukemia deaths compared to expected rates is statistically significant.

Statistical significance is determined on the basis of two related issues:

- the starting hypothesis for the study; and
- the confidence interval associated with a specific study result.

Starting hypothesis

15. It has long been clear that radiation of the type emitted by nuclear stations - ionizing radiation - can cause childhood leukemia. In fact, in the study of radiation-induced cancers, childhood leukemia cancers appear to be one of the single greatest detectable adverse health effects of ionizing radiation. Thus, epidemiologically, childhood leukemia cancers are one of the most obvious indicators of radiation effects.

16. Additionally, as noted in the AECB study, a number of studies in other countries have found an increased risk of childhood leukemia around nuclear plants (Introduction, page 1).

In this context, the issue for the AECB study is whether there was an increased risk of childhood leukemia around Canadian nuclear facilities. As stated by the authors in the Phase I study:

"The general objective of this study was to investigate whether or not there exist clusters of leukemia among children born to mothers resident in the vicinity of nuclear facilities in Canada. The specific objectives of the study were to determine (a) whether or not there have been elevated frequencies of leukemia in children who were born to mothers residing in the vicinity of nuclear facilities in

> Ontario, and (b) whether frequencies have been greater by residence at time of birth than by residence at time of death." (p.2)

18. This situation of examining whether there is an increased risk of leukemia contrasts with a situation of initial neutrality. A situation of neutrality exists where one has <u>equal</u> reason to expect that nuclear facilities may decrease leukemia risks as increase such risks.

19. The starting point for the AECB study was appropriately not neutrality. As stated clearly in its objectives, the focus was on whether or not there was an increase in leukemia deaths.

20. In statistical terms, the difference in starting hypotheses is critical. Where one has a starting hypothesis of, for example, increased risk, the study is oriented towards establishing whether or not there is statistically significant increased risk. As there is a single orientation to the study, the test for significance is termed a single-tail test.

21. By contrast, where one has no data to support any hypothesis, one starts with a position of neutrality. In this situation, the study is oriented to establishing whether there is any departure - increased risk or decreased risk - from what is normally the case. As this kind of study gives equal weight to two opposite orientations - an increased occurrence or a decreased occurrence- its test for significance is termed a two-tail test.

22. Having regard for these accepted statistical principles, the AECB study should use a one-tailed test for significance, not a two-tailed test. The authors of the AECB study explicitly recognize this point at page 7 of their Phase I Report:

> "It should be noted...that the existence of the prior hypothesis of increased risk in the vicinity of nuclear facilities calls for the use of a one-tailed, rather than a two-tailed test of statistical significance."

<u>Confidence intervals</u>

23. In radiation cancer epidemiology, a one-tail test is coupled with a 90% confidence interval to determine statistical significance. This approach is illustrated in two international studies that are among the most important radiation cancer studies to appear in the last several years:

> (1) The leading international study of cancer in radiation workers is the study by E. Cardis and others, *Combined Analyses of Cancer Mortality Among Nuclear Industry Workers in Canada, the United Kingdom and the United States of America* (World Health Organization, IARC Technical Report No.25 (1995); also *Radiation Research 142*, pp.117-32) [Attached as Exhibit "D" to my affidavit is a

true copy of this *Radiation Research* article.]

(2) The most recent and important study for radiation risk assessment is the A-bomb survivors cohort study by Pierce, DA, and others, *Studies of the Mortality of Atomic Bomb Survivors* Report 12, Part 1. Cancer: 1950-1990; summarized in (1996), Vol.146 *Radiation Research* 1-27. These findings provide the basis for radiation standards around the world. [Attached as Exhibit "E" to my affidavit is a true copy of this *Radiation Research* article.]

24. By contrast, a 'neutral' hypothesis uses a two-tailed test and a 95% confidence interval to determine statistical significance.

25. Thus, depending on whether the starting hypothesis involves use of s single-tailed or double-tailed test, one uses a different confidence interval.

26. In para.10 of her affidavit, Ms. Fraser comments that the "established scientific statistical criteria" for this study was to use a 95% confidence interval. I disagree with this statement. The appropriate statistical standard for studies like this is a 90% confidence interval because the study's starting hypothesis involved a one-tailed test of statistical significance.

Conclusion on statistical significance

27. In my opinion, the AECB study fails to follow appropriate statistical methods for analyzing radiation cancer epidemiology data. This results in understating the statistical significance of the 40% observed increase in childhood leukemia rates around the Pickering and Bruce nuclear power plants. The AECB study fails in the following ways

(1) the Phase I study used a single-tail hypothesis test for some nuclear facilities, but inappropriately failed to use this hypothesis for the nuclear power plants;

(2) the Phase I study inappropriately used the 95% confidence interval for the nuclear power plants;

(3) the Phase II study inappropriately used a two-tail hypothesis test, when the context called for a single-tailed hypothesis test, as set out in the Phase I study; and

(4) the Phase II study inappropriately used the 95% confidence interval for the nuclear power plants.

28. When the AECB data is considered appropriately (i.e., a single-tail hypothesis and a 90%

confidence interval), the study shows a statistically significant excess leukemia rate in the vicinity of the two nuclear stations studied. The AECB's use of the 95% confidence interval, which is inappropriate in my opinion, has the effect of denying a statistically significant increased risk.

29. In sum, if the AECB study had used the internationally-accepted method for studying radiation induced cancers, of a single-tailed test and a 90% confidence interval, the present excess rates of childhood leukemia deaths near the Bruce and Pickering nuclear power plants would be considered statistically significant.

30. The conclusion that the AECB study provides statistically significant results for the nuclear power plants appears to have been communicated to the AECB as early as 1991. In 1991, a Canadian organization - Energy Probe - appears to have submitted a technical analysis on this point to the AECB. Further, it appears that the AECB subsequently retained two outside reviewers to examine this conclusion. Each reviewer came to different conclusions, with one reviewer Professor Park Reilly, agreeing with the Energy Probe analysis and the conclusion of statistical significance (Reilly, p.5). Attached as Exhibit "F" to my affidavit is a true copy of a package received by me that was assembled by Energy Probe documenting these communications to and from the AECB.

31. I disagree with Ms. Fraser's conclusion in para.22 that the observed 40% excess in childhood leukemias found in the AECB study was "in fact, most likely due to chance." In my view, the AECB study clearly indicates a statistically significant excess of leukemia mortality among children 0-14 years of age within 25 km of the two nuclear facilities. Further, in my view, it is simply incorrect to conclude that a situation which has less than a 5% probability of being due to chance is "most likely" due to chance.

(b) Trends over time

32. One important means of assessing trends over time is to compare leukemia deaths before nuclear power plant operation with deaths after. The authors of the AECB study carried out this work for the Pickering nuclear station, but not the Bruce station. I have two comments:

(a) Factually, the data is incomplete as this before and after comparison was not done around the Bruce station. The authors of the AECB study suggest that the rationale for not doing this work is that the population around the Bruce area was "relatively small" (Phase II Report, p.12). I believe that the absence of this before and after data for Bruce is unfortunate and not justified by reference to a small population.

(b) For the comparison that was done, that around the Pickering station, the leukemia rate before operations was

essentially the same as expected.

33. Thus, there is no evidence of an increase in childhood leukemia rates before the activation of the two plants. However, the study data shows a significant excess in childhood leukemias after operations began.

Follow up studies

34. Ms. Fraser suggests that the AECB followed up its child leukemia studies with a further AECB study. In my opinion this follow-up study is inadequate. I believe that at least four follow-up studies should be conducted:

(1) Follow-up on the specific issue of leukemia around these sites. The first study ended with 1987 data. It is now 1999. There are thus several years of data to follow-up on.

(2) Follow-up on other reactors. I understand that all Canadian domestic reactors use the same basic technology - CANDU technology developed by Canada. In addition to the Bruce and Pickering reactor complexes, I understand that there are other CANDU reactor complexes in Canada, including a reactor complex in Darlington Ontario and other CANDU reactors in the provinces of Quebec and New Brunswick (AECB Phase I, p.2). The first study was restricted to the Pickering and Bruce reactors. There is no identified study of the other reactors.

(3) Follow-up on the location of cancers. The first study states that its parameters allowed no differentiation of cancer locations inside a 25 km radius of the power stations. It would be important to assess where the leukemia risk is higher at closer distances.

(4) Follow-up on exposure levels. The AECB study provides no exposure data for people nearby the nuclear power facilities. I understand the proposed project is expected to release neutrons as well as gamma radiation. I would note that there is very interesting German work being done on the issue of neutron exposures and their relative biological effectiveness (RBE) which suggest that neutron exposure may be more effective than current RBE estimates of 10 to 15 at low dose exposures. The German work suggests that the current multiplier may need to be greatly increased. Attached as Exhibit "G" to my affidavit is a true copy of a recent article discussing these issues.

35. I would rate any of these four follow-up studies as more directly relevant to the AECB leukemia study than the one follow-up study done by the AECB identified by Ms. Fraser. I have reached this conclusion, in part, because the authors of the first study suggested that their data did not support the hypothesis examined in more depth in this single follow up study (Ex.49, p.55: "Unlike the large difference between the mortality ratios obtained by Gardner *et al*... for the birth cohort and the school cohort in the vicinity of the Sellafield facility, in Ontario there was no consistent pattern of higher mortality ratios based on residence at birth rather than death."). There is, by contrast, no indication in the AECB study of what the answers are to the four matters set out above by me as deserving further study.

36. I also believe that it is inappropriate for Ms. Fraser to rely on the population mixing hypothesis, as she does in para.23. Ms. Fraser's thesis is based on a British study asserting that population mixing is a cause of cancer clusters near the Sellafield nuclear reprocessing plant in the United Kingdom. In my opinion, it is inappropriate to assert that population mixing is responsible for cancer clusters around Canadian nuclear reactors absent Canadian data relating to population mixing in the vicinity of these nuclear plants. In my view, this hypothesis would require a further Canadian follow-up study using Canadian data on this topic before it may be judged applicable in Canada.

37. Further, as concerns the British situation, it is simply not true that the British hypothesis has been 'demonstrated' as she sets out in para.23. The fact that population mixing can be a cause of childhood leukemia does not demonstrate that it was the cause of the childhood leukemias near the British reprocessing stations. For example, I note that the authors of the British study and Dr. Richard Doll, upon whom Ms. Fraser appears to rely (see her paras.19-23), both recognize that the population mixing hypothesis most likely appears to account for some but not all of the elevated levels of leukemia around the British nuclear reprocessing facilities: see her Ex.5, pp.144 (Summary), 149; also, Ex.6, p.4.

Other studies in other countries

38. Ms. Fraser appears to place considerable reliance upon studies of different nuclear facilities in other countries, especially Sellafield in England - which has been extensively studied. Yet it is not clear from her affidavit or other studies that the British fuel processing facilities (such as at Sellafield or Dounreay, Scotland) emit the same type and quantity of radiation emissions as the Canadian nuclear reactors. This makes epidemiological extrapolation difficult.

39. I also note that the area around the German Krummel site - which is a nuclear power plant - has been subject to unexplained excesses of childhood leukemias within 10 km of the site arising since its establishment. Whether these increases are due to radiation, or chemicals, or possibly some other cause, is not yet known. Further, unlike the British

areas, this German site has not received extensive population mixing. This indicates that the British "infectious agent" hypothesis is not a complete explanation for observed increases around other countries' nuclear facilities.

40. Thus, there are a number of issues which point away from using other countries' studies for the Canadian context:

(1) Technologies. The Canadian study compares two reactors using CANDU technology. For reasons indicated above, it is not clear to me that other nuclear facilities - such as the English nuclear reprocessing facilities - will have the same effects as these reactors. Indeed, it is not clear to me that other non-CANDU nuclear reactors should be presumed to have the same effects.

(2) Emissions. The Canadian studies compare two reactors at a range of 25 km. Yet the AECB study provides no information on the radiation emissions from the nuclear power plants (e.g., beta, gamma, and neutron). Further, the emissions data from other studies cited by Fraser is also incomplete. For example, the German study cited by her (Ex.3), provides no emissions data on the Krummel situation or the other German nuclear plants. Absent such information, it is difficult to compare the results of studies in other countries with the AECB study results.

(3) Radiation dose. Other studies have sought to relate dose to cancer findings. Absent specific numbers suggesting similar radiation dosages (in total or in specific forms of radiation - alpha, beta, gamma, neutron), it is not clear to me that other studies are comparable.

(4) Populations. A basic population question is whether the populations around Canadian nuclear sites resemble those around nuclear facilities subject to other epidemiological studies. The British studies cited by Ms. Fraser suggest that population mixing is a particularly important matter to appreciate in comparing populations; the German situation suggests population mixing is not central to its leukemia excesses. Absent facts on population showing similar populations, it is not clear to me that other studies are comparable.

41. In sum, I believe that the best approach to the Canadian studies is to use Canadian data and Canadian follow-up studies. Studies in other countries are relevant, particularly in identifying hypotheses meriting further study in Canada, but I do not believe studies in other countries may be presumed to "demonstrate" answers to Canadian data.

Increased prostate cancer rates in Bruce County

42. At paragraph 28 of her affidavit, Ms. Fraser responds to the incidence of increased prostate cancer in Bruce and Grey counties. I understand that the Bruce reactor is located

in Bruce county and is proximate to Grey county. Ms. Fraser states that "existing occupational studies do not provide convincing evidence to suggest that nuclear workers as a group exhibit excess prostate cancer attributable to radiation exposure." It is unclear from this choice of words whether Ms. Fraser was aware of British studies showing elevated rates of prostate cancer in its nuclear workers. Attached as Exhibit "H" to my affidavit is a true copy of four papers on this topic:

- Beral et al., (1985), 291 British Medical Journal 440-447;
- Beral et al., (1988), 297 British Medical Journal 757-770;
- Fraser et al., (1992), 67 British Journal of Cancer 615-624; and
- Rooney et al., (1993), 307 British Medical Journal 1391-1397.

43. Having regard for these British studies, the Canadian data would appear to merit further study for its potential relationship to radiation exposure.

I make this affidavit in support of an application by the Inverhuron & District Ratepayers' Association for certain relief in respect of the Bruce Used Fuel Dry Storage Facility Environmental Assessment and for no other purpose.

DR. DAVID HOEL

Sworn before me this 9th day of December, 1999
at the City of Charleston, in the State of South Carolina,
in the United States of America

Notary/ Commissioner **for taking affidavits**

Jamie M. Williams
Commission Expires: 09/23/02